

Appendix E

Review, Approval, and Authorization Levels for Safety Procedures

This appendix can be used to determine the level of management required to authorize, review, and approve a given safety procedure. The number of reviewers may be increased as appropriate. A reviewer provides technical input to the document to insure that it is accurate and meets the technical, regulatory, and legal requirements, as appropriate. The person who concurs with the procedure is agreeing that the activity and the FSP or OSP are appropriate for his/her facility or people. The “approver” is the person authorized to approve the procedure and is responsible for the activity.

Any person serving as a Responsible Individual for an activity requiring a safety procedure or analysis shall NOT have approval authority governing the conduct of that activity.

NOTE: Changes in operations with no adverse ES&H implications (e.g., personnel changes) may be approved by the individual approving the original procedure (or an authorized designee) and the ES&H Team Leader.

E.1 FSP Review and Approval

The reviewers listed below are typical, but adjustments may be necessary in some cases. Reviewers and approvers may designate others to perform the review, but they retain responsibility for the effectiveness and timeliness of the review process.

Reviewers

- ES&H Team Leader
- Facility Manager/Supervisor
- Assurance Manager
- At Site 300, the Site 300 Manager
- Materials Management Section (if appropriate)
- LLNL Institutional Review Board (if appropriate)
- Plant Engineering Maintenance and Operations Division (PEMOD) Leader

Approver

- Facility AD

E.2 OSP Review and Approval

Below are the review and approval levels for all LLNL OSPs.

Level A. The following are examples of activities that require Level A review and approval:

1. An experiment involving nuclear fission in a self-sustaining chain reaction.
2. Use or storage of more than 45 percent of the minimum critical mass of a given form of fissile material.
3. Requests for a variance from mandatory codes, standards, and regulations (see Chapter 1 of the *Health & Safety Manual*) and the promulgation of its approval using an OSP; or requests for a change in a legal or DOE-prescribed safety analysis document (e.g., safety analysis report, TSR, and Environmental Impact Statement).
4. An activity that takes place offsite for which LLNL personnel have full or partial operating responsibility and an OSP is required.
5. An activity that may produce undesired effects (i.e., death or injury to a member of the general public, damage to non-DOE property, and/or damage to the environment).
6. Any experiment involving human subjects.

Reviewers

- Responsible Individual
- The supervisor of matrixed personnel involved in the activity
- Facility Supervisor or Manager
- ES&H Team Leader
- Materials Management Section (if appropriate)
- LLNL Institutional Review Board (if appropriate)

Concurrence

- Facility AD (or designated alternate), if the activity is conducted in a facility under the management of another AD, or the Facility Manager
- Safety representative at the offsite location where the operation is being conducted
- At Site 300, Site 300 Manager

Approver

Program AD (or designated alternate) for the program conducting the activity

Level B. The following are examples of activities that require Level B review and approval:

1. An activity that requires an OSP, but for which approval is not specified as Level A nor is the activity included in Level C.
2. An operation involving fissile or radioactive material.
3. An operation involving explosives.

Reviewers

- Responsible Individual
- The supervisor of the matrixed personnel involved in the activity
- ES&H Team Leader
- Materials Management Section (if appropriate)
- Peer-review committee (explosives operations at the Livermore site)

Concurrence

- Facility Supervisor or Manager
- At Site 300, Site 300 Manager

Approver

The Program Division Leader, Department Head, or Program Leader for the activity

Level C. The following are examples of activities that require Level C review and approval:

1. A change to an existing OSP that does not increase the residual risk level.
2. The first extension of the expiration date of an existing safety procedure that does not include any other changes.
3. An OSP for an activity that meets all the requirements of the *Health & Safety Manual* and *Environmental Compliance Manual*, but is required only because of a management directive.

Reviewers

- Responsible Individual
- The supervisor of the matrixed personnel involved in the activity
- ES&H Team Leader

Concurrence

- Facility Supervisor or Manager
- At Site 300, Site 300 Manager

Approver

The Program Division Leader, Department Head, or Program Leader for the activity

E.3 Special Reviews for Specified Hazards

Explosives. A peer-review committee shall review the draft procedure for explosives operations. Each Directorate may establish its own list of peer-review personnel or obtain assistance from the High Explosives Safety Committee. The area of explosives expertise for each topic (e.g., synthesis or initiation) shall be indicated next to name of each person on the list. Individuals on this committee must be qualified and knowledgeable of explosives operations. The committee shall document its comments

on a separate pre-publication form, and use a separate signature page marked “Peer Review” for the final safety procedure. This page shall be retained by the ES&H team with the original safety procedure.

Fluorine. Experiments involving fluorine that pose a greater risk of harm than that caused by a 250-ft³ mixture of expanded volume quantities of 10% fluorine and inert gas must be reviewed by the Laboratory Pressure Safety Committee.

Human Subjects. Any experiment that involves the use of human beings or tissue from humans must be reviewed by the Laboratory’s Institutional Review Board. Contact the Biology and Biotechnology Research Program Office for additional information.

Animals. Any experiment that involves the use of live animals must be reviewed by the Institutional Animal Care and Use Committee. Contact the Biology and Biotechnology Research Program Office for additional information.

Recombinant DNA. Any experiment that involves the use of recombinant DNA must be evaluated by the Institutional Biosafety Committee.

Offsite Jurisdiction. Activities that take place at an offsite location may be subject to additional reviews by jurisdictions having authority over the activity. For example, use of a high-powered laser to conduct astronomical or meteorological experiments may require the approval of the Federal Aviation Administration. These reviews should be obtained well in advance and documented in the safety procedure.